



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/828,964

04/21/2004

Weston F. Harding

P-5540C1

5397

26253 7590 12/26/2008
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
1 Becton Drive
MC 110
Franklin Lakes, NJ 07417-1880

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,964	Applicant(s) HARDING ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3763

DETAILED ACTION

Response to Amendment

Amendment filed on 9/15/08 has been entered.

Claims 32-37 are present for examination.

Claims 1-31, 38-39 are cancelled.

Specification

A substitute specification is required pursuant to 37 CFR 1.125(a) because Examiner notices that the current Specification filed in 4/21/04 does not match (i.e. the paragraph number) with the PG-Pub 2004/0199126.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "the portion of the slit in the distal portion of the septum is open in the unstressed condition" of claims 34 and 37 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The Figs. 37 or 38 does not clearly show how the distal portion of septum is open in the unstressed condition.

Art Unit: 3763

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

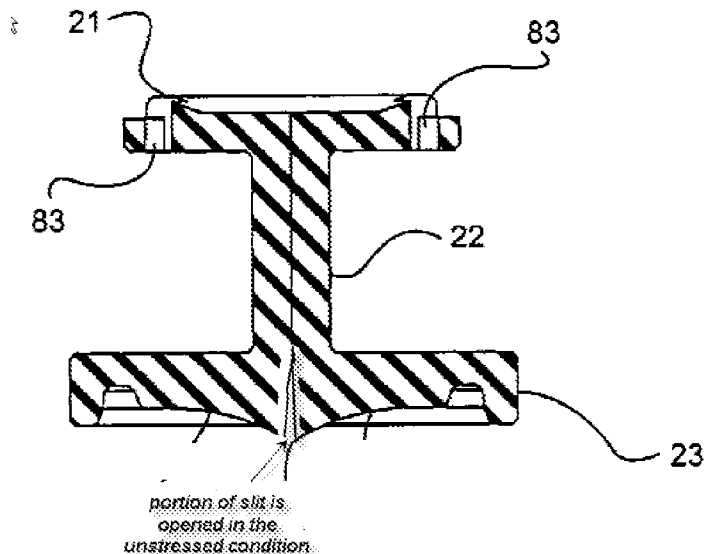
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In Fig. 34, it clearly shows that the slit 25 the septum 20 is completely closed from the proximal to distal portion in the unstressed condition (normal state without objected inserted into the septum 20, Fig. 34). This feature is opposite with the limitations as recited in claims 34 and 37. The Fig. 34 should be looked like Fig. below as limitation "the portion of the slit in the distal portion of the septum is open in the unstressed condition" recited in claims 34 and 37.

Art Unit: 3763



Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-33, 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by McPhee (US 5,199,948).

McPhee discloses a needleless luer access connector comprising: a housing 13 having a top portion defining an inner opening, a channel defined by at least one sidewall extending from the inlet opening and having a cross section, and a bottom portion defining an outlet opening extending from the

Art Unit: 3763

channel; a septum 15 disposed in the housing, the septum having a proximal portion, a medial portion having an external surface and a cross section less than a cross section of the top portion 35a and less than the cross section of the channel and a distal portion defining a substantially circular cross section in its unstressed condition (Fig. 1); a longitudinal slit 33 extending through the septum from the proximal portion through the medial portion and into the distal portion; and wherein the channel has substantially elliptical cross section having a major and minor axis along at least a distal portion thereof and the distal portion of the septum is located in and restrained by the distal portion of the channel such that the distal portion of the septum is biased into a substantially elliptical shape by the distal portion of the channel and a portion of the longitudinal slit 33 in the distal portion of the septum is closed (Figs. 1-2).

Claims 32-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Jepson et al. (US 6,344,033).

Jepson discloses a needle less access connector comprising: a housing 1418 having a top portion defining an inner opening, a channel defined by at least one sidewall extending from the inlet opening and having a cross section, and a bottom portion defining an outlet opening extending from the channel; a septum 402 disposed in the housing, the septum having a proximal portion 404, a medial portion 406 having an external surface and a cross section less than a cross section of the top portion 35a and less than the cross section of the channel and a distal portion defining a substantially circular cross section in its unstressed condition (Fig. 1); a longitudinal slit 414 extending through the septum from the proximal portion through the medial portion and into the distal portion; and wherein the channel has substantially elliptical cross section having a major and minor axis along at least a distal portion thereof and the distal portion of the septum is located in and restrained by the distal portion of the channel such that the distal portion of the septum is biased into a substantially elliptical shape by the distal portion of the channel and a portion of the longitudinal slit 414 in the distal portion of the septum is closed (Figs. 13).

Regarding claims 34 and 37, as best as understood, the portion of the slit in the distal portion 410 of the septum is opened in the unstressed condition (Fig. 13).

Art Unit: 3763

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-37 of U.S. Patent Nos. 6,908,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not structurally distinguishable from the claims in the patents. The device of instant claims are fully disclosed and covered by the U.S. Patent Nos. '459. In other words, the scope of the instant claims is broader than that of '459.

Response to Arguments

Applicant's arguments filed 9/15/08 have been fully considered but they are not persuasive.

1. Applicant argues that mcPhee does not focus on closing longitudinal slit 33 at the lower or distal end of the septum.

In response, Claims 34 and 37 involve 112th rejection issue. Please see rejection above for more details. However, McPhee fully discloses all the limitations of claims 32-33 and 35-36.

2. Applicant argues about the double patenting rejection. Claims 1-7 of the '459 patent require a rib formed on the external surface of the media portion such that the rib is displaced from the barb until the male luer taper is inserted into the slit.

Art Unit: 3763

In response, the device of instant claims are fully disclosed and covered by the U.S. Patent Nos. '459. In other words, the scope of the instant claims is broader than that of '459.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763